Dear Dr. Berwick,

The Association of Public Health Laboratories (APHL) is concerned about the tremendous financial burden and additional time it will take for public health laboratories (PHLs) to develop, initiate and implement processes for patient access to testing results. The proposed rule will place additional stress on PHLs, which are already struggling because of workforce reductions and declining budgets.

We therefore respectfully request the following:

- Additional time to put the necessary processes in place to comply with this rule. The additional time will reduce the immediate financial burden it imposes; we suggest that the effective date be 2014 to correspond with the proposed deadline for electronic laboratory reporting to medical records.
- Additional guidance on how this rule applies to reporting of public health surveillance or outbreak investigation testing results.
- Explicit language that clarifies that the public health laboratory is not responsible for, or expected to interpret results for individual patients.
- Clarification that this rule only applies to patient testing, not to food or environmental testing.
- Confirmation that this rule applies only to the primary laboratory to which the specimen was submitted, not to a referring laboratory.

APHL appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS; Office for Civil Rights (OCR), HHS proposed rule that would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon a patient’s request, the laboratory may provide access to completed test reports that, using the laboratory’s authentication process, can be identified as belonging to that patient. We would be happy to provide specific examples on the difficulties imposed from implementation of this rule as written.

Sincerely,

Scott J. Becker, MS Executive Director
Association of Public Health Laboratories
APHL represents governmental laboratories that detect and monitor public health threats. APHL’s members include state, territorial, and local public health laboratories; state environmental testing laboratories, state agricultural and food safety laboratories; and individual scientists, public health officials, and academicians.